HKS820

Intense Pulse Light
Radio Frequency

User&Training Manual

CE LVD tested EMC tested ROHS

HKS820
Intense Pulse Light RadioFrequency
User&Training Manual

Intense Pulse Light Safety Guidelines

The Following information is provided for the correct utilization of IPL Skin treatment system.the Information includes not only the accident protection regulations the products comply with,but also the effective regarding proper use of the products.

1)Electric safety regulation
The EMC Directive 89/336/EEC amended by 92/31/EC &93/68/EECEN55015:2000+A1+A2/LUM200704025/ EMCEN61000-3-2:2000+A2/LUM200704025/EMCEN 61000-3-3:1995+A1+A2/LUM200704025/EMCEN61547: 1997+A1/LUM200704025/EMC

2)Material ROHS test2002/95/EC
Restriction of use of certain Hazardous Substance in Electrical&electronics Equipment/ROHS.

3)Electromagetic radiation safety regulation LVD/ EN60601-1:2006/AGC10430904GZ05E3EMC/EN60601 -1-2:2001+A1:2006/AGC10430904GZ05E1

4)ISO13485:2003 MEDICAL/33021200005459

5)ITC MEDICAL CE
IPL SKIN TREATMENT SYSTEM belongs to Ⅱa according to MDD directive,It designed according to EN 980:2003; EN 1041:1998; EN ISO 14971:2007; EN 60601-1-2:2007; EN 61000-3-2:2006;EN 61000-3-3:1995+A1:2001+A2: 2006; EN 60601-2-22:1996;
EN 60601-1-4-1996+A1-1999; EN 60601-1:2006.

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Certificate

Certification body of the management system No. 3002
Institute for Testing and Certification, Inc.
T. Bati 299, 764 21 Zlin, Czech Republic
www.itczlin.cz

CERTIFICATE

No. 09 0154 SJ

We confirm on the basis of a performed audit that company

NINGBO RUIPU MEDICAL EQUIPMENT CO., LTD.
Gulin Industrial, Yinzhou, Ningbo, China
Company Reg. No.: 330212000054529

has implemented and documented a functional quality management system in compliance with the requirements of the standard

EN ISO 13485:2003

Covering the following activities:

Production and Distribution for IPL Skin Treatment System, Radio Frequency and Laser Apparatus for Medical Use

The Certificate is issued on the basis of the results mentioned in Audit Report No. 233401385/2009. The Certificate validity is conditioned by postive results of surveillance audits, which the certified company committed to undergo.

Date of issue: 27. 07. 2009
Valid until: 31. 07. 2012

Ing. Pavel Vaněk
Head of Certification Body

Notified Body No 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlin, Czech Republic – www.itczlin.cz

EC CERTIFICATE

No. 09 0739 QS/NB

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws), certifies that the medical devices of Class IIa:

IPL SKIN TREATMENT SYSTEM
Models: HKS801, HKS801B, HKS801C, HKS801E, HKS807A, HKS807B, HKS811, HKS811B, HKS820, HKS820B

manufactured by company

NINGBO RUIPU MEDICAL EQUIPMENT CO., LTD.
Gulin Industrial, Yinzhou, Ningbo, China

is manufactured under conditions fulfilling the quality system requirements of Annex V, Section 3.2 of the Directive 93/42/EEC, as amended.

The Notified Body No. 1023 has performed an audit of the above products quality system covering the design, manufacture and final inspection of the certified products. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex V, Sections 3.3 and 4 of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No.803000052/2009, which is enclosed to this Certificate.

This Certificate is issued under the following conditions:

1. *It applies only to the quality system maintained in the manufacture of above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.*
2. *The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the* ***29th October 2014*** *at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After fulfilling the relevant EC legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking followed by the number of the Notified Body according to this example*

CE 1023

Issued in Zlin, on 30th October 2009

RNDr. Radomír Cabelík
Representative of the Notified Body No. 1023

Question

Why is IPL better than other treatments?
In addition to treating multiple symptoms and locations in each session, IPL is gentle, non-invasive and safe. Because of this, there is no "down time." You see results in the complexion and the skin texture of the entire face. You can return to your normal routines and activities immediately. In fact, many people even schedule their sessions during their lunch break. Additionally, IPL treatments are customized to your specific skin type and color, providing the best possible results.

What areas can be treated with IPL systems?
The IPL System can remove hair from all parts of the body including the face, legs, arms, underarms, and back. It can also treat sensitive areas like the chest, nipples and bikini line.

What do IPL treatments feel like?
As the name implies, the IPL hand-piece cools and sooth es as it glides along your skin. When the pulse of lights delivered, some patients experience a mild pinching or stinging sensation. No local anesthesia or pain medication is typically required, however some patients may prefer to use a topical anesthetic when sensitive areas are treated.

How many treatments will I need?
Most areas require 3-6 treatments, but the number of IPL treatments you may require for optimal long-term benefits depends on various factors such as your hair thickness, the area treated, and your hair growth

Question

cycle. Interestingly, not all hairs are actively growing at the same time, but actually go through three distinct phases; growth, regression, and resting. IPL systems work by disabling the hair that is principally in the active growth phase at the time of treatment. Since other hairs will enter this active growth phase at different times, additional treatments may be necessary to disable all of the hair follicles in a given area.

How is IPL used to treat benign vascular lesions?
Aging, sun exposure and other factors can cause the appearance of broken capillries and blood vessels on the face known as telangiectasias, which appear as spider veins. Sometimes broken capillaries can cause a diffused redness in the skin, called erythema, a source of social embarrassment for many people. Rosacea is a common skin condition that is characterized by diffused erythema. All of these conditions

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1.Product Information

1.PRODUCT INFORMATION

APPLICATION
*Hair removal
*Skin rejuvenation
*red face, red nose, couperosis, spider veins.
*age spots, sun spots, pigmentation troubles
*Acne
*Skin tightening and lifting
*Wrinkle reduction
*Systemic collagen regeneration

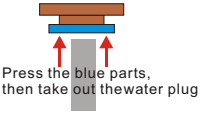
FEATURES
*1handle
Big handle:15*50mm with 5filter
640-1200nm for hair removal
590-1200nm for red face, red nose, couperosis, spider veins.
560-1200nm for Skin rejuvenation
430-1200nm for Acne optional
480-1200nm for age spots, sun spots, pigmentation troubles optional
750-1200nm for hair removal in Dark Skin optional
*Lamp longevity:60000shots
*Energy:15-50J
*Pulse Number:1-15adjust
*Pulse Width:1.0-20.0
*Pulse Delay:1-50
*Shot period:2-5second adjust
*Display:8.0 inch Touch display
*Voltage:110V or 220V
*Power:1000W
*Cooling system:Wind+water+semiconductor
*RF Frequency:1/3/10MHz Variable frequency
*RF Power:80W
*RF Probe:2handle with 3probe
*Pakcge size:110*62*62cm
*Weight:56kg

2.Installation Alignment and operation procedures

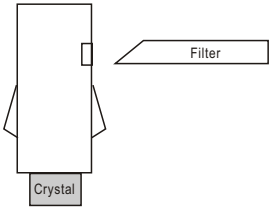
2.1 Open the Package and checking all parts.

2.2put the handle holder on machine by screw.then connect well the handle in back of machine.

2.2 put the water to Input,when water is out of overflow means the water tank is full

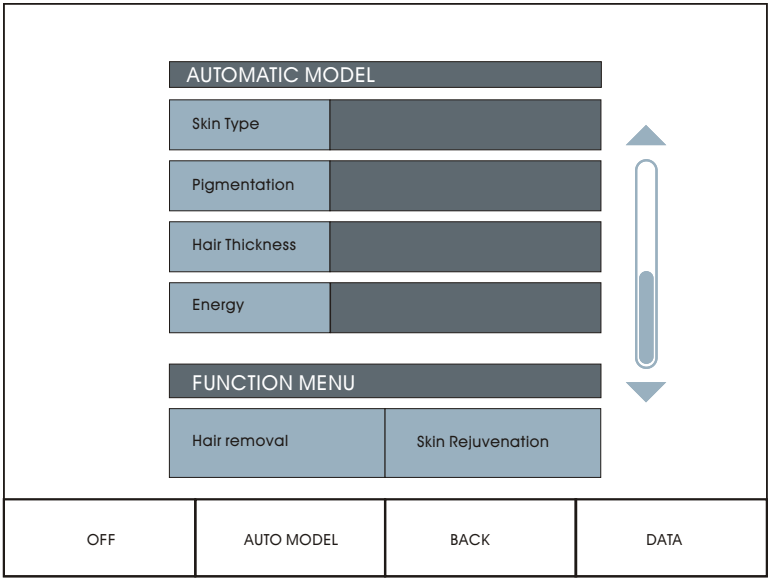


2.3 Put the filter in handle



3.Operate the Device

3.1 Auto interface



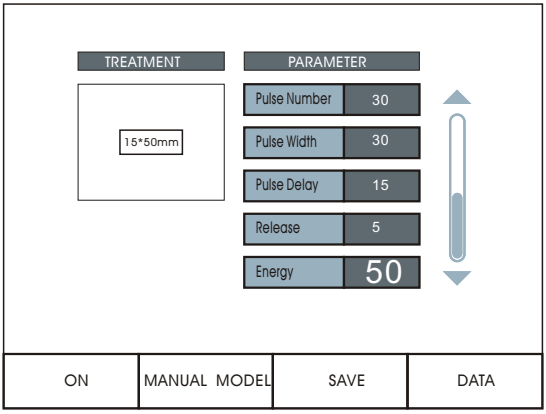
Skin Type: Ⅰ-Ⅱ White Skin Ⅲ Ⅳ Dark Skin

Pigmentation:None Light Medium Intense

Hair Thickness:Thin Medium Thick

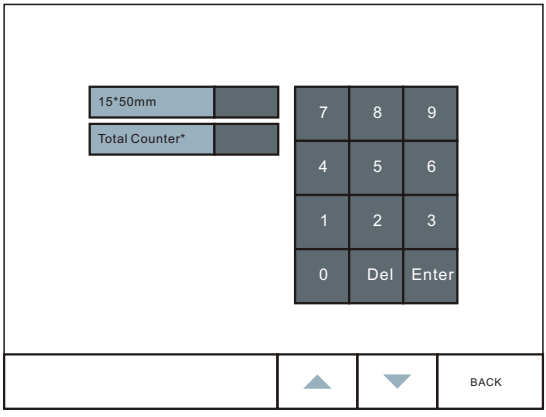
3.Operate the Device

3.2 Manual interface



Save:Save the parameter for current
Release:time for each shot distance

3.3 Data interface

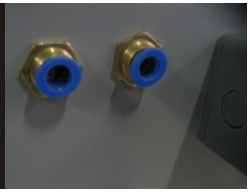


15*50mm:current shot account,press it will be 0
total couonter:all shot account,need input password for 0

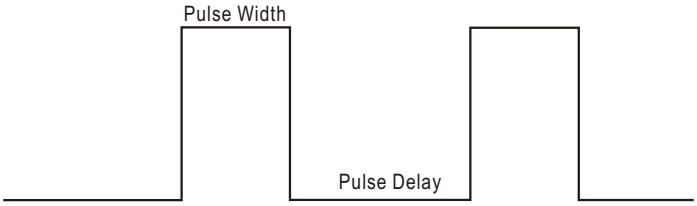
3.Operate the Device

3.3 Operating&setting

Before turn on machine, must take out the water Plug from machine back.



Choice one model language in Screen.The system will enter Auto model.In Auto model,the system have memory right parameter for many treatment.Only need chice right Skin type,Pigment,Hair thichness,then press the READY,the Machine can start to work.Manual model,User can input right parameter to fix sufferer treatment.Choice different filter to make different treatment.User Data show the current shot amount and total amount.
Delete total shot amount need password.



3.4 Finish the treatment.
Frist need press the ON in screen,make the lamp off.Then turn off the key switch+urgency button+main electric switch.
Do not let the lamp be light when the user leave for long time.

4.Treatment Parameter

Dark hair by lower width
Light hair by higher width
thickness hair by higher delay and lower energy
thin hair by lower delay and higher energy
dark skin by higher delay and lower energy
light skin by lower delay and high energy
When add the width that can not reduce the energy
when reduce the width that can not add the energy

SKIN TYPE	A	I - II
	B	III - IV
PIGMENTATION	1	none
	2	light
	3	medium
	4	intense
HAIR THICKNESS	C	thin
	D	medium
	E	thick

Skin rejuvenation				
	Pulse Number	Pulse Width	Pulse Delay	Energy
A1	1	9.7	0	28
A2	1	9.2	0	27
A3	1	8.8	0	26
A4	1	8.4	0	25
B1	2	9.2	10	26
B2	2	8.8	10	25
B3	2	8.4	15	24
B4	2	8.2	15	23

4.Treatment Parameter

Hair Removal				
	Pulse Number	Pulse Width	Pulse Delay	Energy
A1C	1	9.5	0	36
A1D	1	8.5	0	35
A1E	1	7.5	0	33
A2C	1	8.5	0	34
A2D	1	7.5	0	33
A2E	1	6.5	0	32
A3C	2	7.5	10	32
A3D	2	6.5	10	31
A3E	2	6	10	30
A4C	3	7	15	30
A4D	3	6	15	29
A4E	3	5.5	15	28
B1C	3	9	5	35
B1D	3	8	5	34
B1E	3	7	5	33
B2C	3	8.5	10	33
B2D	3	7.5	10	32
B2E	3	6.5	10	31
B3C	3	7.5	15	31
B3D	3	6.5	15	30
B3E	3	5.5	15	29
B4C	5	6.5	17	29
B4D	5	6	17	28
B4E	5	5.5	17	27

5.Treatment Procedure

5.1 Shave the hair on skin and left hair be 1-2mm.

5.2 Put the Gel on skin,Gel Thickness is around 1mm.

5.3 Touch well the crystal on skin.

5.4 After treatment,clean the Skin by warm water.

6.IPL Treatment General Knowledge

6.1.Curative effect

After frist one or two treatment,the hair can lost 80%.

After 4-5 treatment,the hair will lost 95%.then no hair grow or less thin hair grow.(Acceptable)

6.2.treatment Caution And the principle

For treatment is that the patient should feel little Acceptable pain.Keep the skin be cool.

Never shot to eyes

6.3. Taboos

a.To avoid using the machine on the abdomen of the pregnant women or women in menses

b.To avoid using the machine on around the parts under which metal,plastic or silicon wee buried.

c.To avoid using the machine on around the medical and electric instrument,such as the hearing aid,heart starter, mechanical heart,etc.

d.To avoid using the machine on the epileptic and those in bad health

e.To avoid using the machine on the wound aroung the treatment area and the areas with metals inside of the body.

f.To avoid using the machine on people who has high blood pressure or diabetes or serious skin diseases or heart diseases, or who is sensitive to electric current,or who is reveiving hormone treatment.

Radio Frequency Safety Guidelines

The Following information is provided for the correct utilization of IPL Skin treatment system.the Infirmation includes not only the accident protection regulations the products comply with,but also the effective prearding proper use of the products.

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2)Material ROHS test2002/95/EC
Restriction of use of certain Hazardous
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3)Electromagetic radiation safety regulation LVD/EN60601-1:2006/AGC10430904GZ05E3EMC/EN60601-1-2:2001+ A1:2006/AGC10430904GZ05E1

4)ISO13485:2003 MEDICAL

Radio Frequency Safety Guidelines

What is Radio Frequency?
RF is used for dermal skin heating with sparing of the epidermis. This will result in non-ablative skin tightening and lifting without injection and surgery.

What is the advantage?
The results are a firmer, refreshed and more youthful face, lifted brows and eyelids, less wrinkles and sharper jaw line again. Eyebags and double chin will improve with this treatment too.

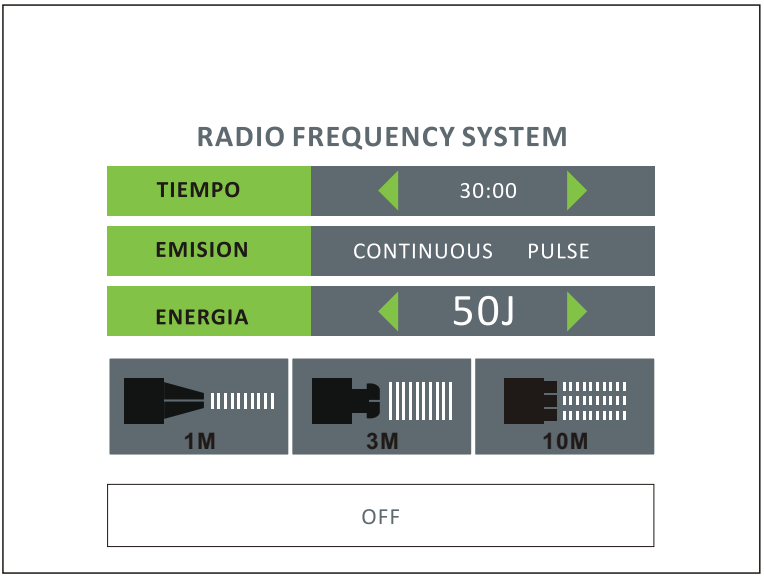
How does it work?
First, heat generated by RF waves shrinks the bundle of collagen under the skin. The collagen becomes shorter and the skin tightens. The second phase begins as the body responds. The collagen will be gradually healed, renewed and even more collagen will be produced. The skin tightens and overall look is improved.

What do I expect during the treatment?
gentle warming sensation is felt throughout the procedures. As there is minimal redness after the treatment, normal activity can be resumed immediately.

How many sessions are required?
1times/2weeks
5-6 sessions is recommended for optimal longer lasting result in treating the wrinkles and lifting the face.

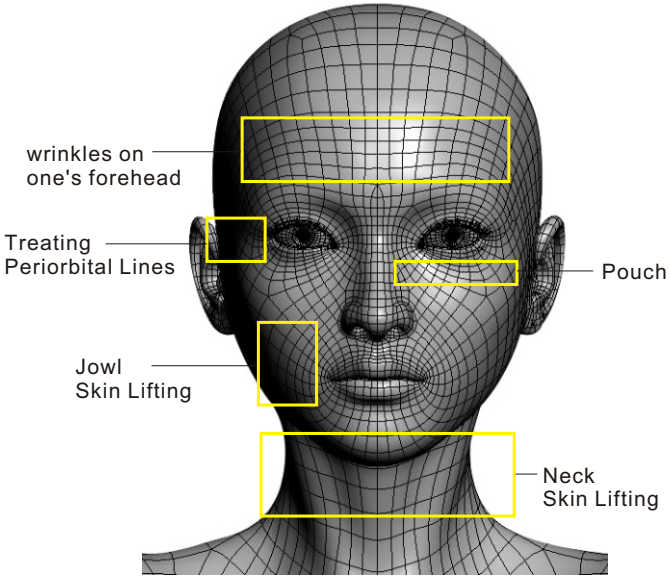
7.RF Operate the Device

7.1 Operate interface



7.RF Operate the Device

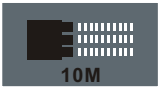
7.1 Operate interface



7.RF Operate the Device

7.2 Manual Model Treatment

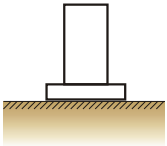
Choice right Probe as you want and adjust the timer and energy,press OFF be ON,the Device start to work.
User need press the switch in handle.

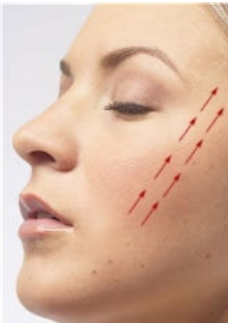
	Adjust Button
	Timer Adjust,Max is 30Minutes
	Continuous or discontinuous
	Energy Adjust
	Choice small bipolar probe 1MHz
	Choice big bipolar probe 3MHz
	Choice tripolar probe 10MHz

8.Treatment Procedure

8.1 .Operateion technigue:Let the treatment probe touch the target area ad mover(Or Slide)from the inner to the outer and round and round and from the lower place to the higher, when you do the treatment ont he upper lid,Pls move a bit more quickly,when the gel on the face get drier,please add some GEL and go on with the treatment.

8.2.Face(Includeing cheek,eye,forhead,lip,neck)
Operation procedure(About 50minutes for whole face,15-20minutes for neck)





a.carry out a skin evaluation before treatment.
B.Clean skin
c.tone skin
d.massage with GEL
e.clean skin
f.smear gel on skin and apply treatment with trobe.
g.let the probe touch the skin and make treatment

Course of treatment:One course of treatments includes 5treatments at an interval of every 10-15days.
Curative effect
After one treatment,the heated subcutaneous fiber shrinks instantly,therefore fins wrinkles are improved,and skin becomes tender,sommth and compact.After onecourse of treatment:the collagen protein is regenerated for long term,skin becomes tender and smooth,wrikles are reduced, and skin is tightened and compact.

8.Treatment Procedure

8.3.Body(striae gravidarum)
Operation procedure(About 60-90minutes for topical area)
a.Carry out a skin evaluation before treatment.
B.clean skin
c.massage with body slimming distillate
d.Smear body slimming diatillate on skin and apply treatment with probe.
e.clean skin
f.let the probe touch the skin and make treatment.
Course of treatment:One course of treatments includes 5 treatments at a interval of every 10-15days.
Curative effect After one treatment,the heated subcutaneous fiber shrinks instantly,therefore skin become smooth,compact and elastic.
After one course of treatment;Skin becomes compact and flabby skin is improved.

9.Treatment Caution

9.1.for treatment is that the patient should feel needling&hot.
9.2.The treatment head must be kept on the skin (sliding); otherwise, the skin will get burned.Before the treatment head leaves the skin, you must loose the button on the head or loose the foot switch.
9.3.When the temperature of the treatment head is over too high, you should stop treatment.The energy you adopt should not be too high; otherwise, the skin will get burned.
9.4.Please carry out skin moisturizing and sun proof cream work after treatments, do not wash faces with hot water (use water under the body temperature), and do not go for hot spring and massage.

10.Treatment Taboos

10.1.The abdomen of the pregnant women or women in menses
10.2.To avoid using the machine on around the parts under which metal,plastic or silicon wee buried.
10.3.To avoid using the machine on the epileptic and those in bad health
10.4.To avoid using the machine on people who has high blood pressure or diabetes or serious skin diseases or heart diseases, or who is sensitive to electric current,or who is reveiving hormone treatment.

11.Treatment Parameter

Therapy Position	Probe	Energy	Mode	Timer
eye side	small	15-20	▬	10
	big	22-28	▬	5
forehead	small	14-17	▬	8
	big	22-28	▬ ▮▮▮▮	5
jowl	Tripolar	20-26	▬	10
neck	big	22-28	▬	15
Abdomen	big	22-28	▬	10
buttocks	Tripolar	22-28	▬ ▮▮▮▮	10
Low-necked	Tripolar	18-24	▬	10
arm	Tripolar	22-28	▬ ▮▮▮▮	10
leg	Tripolar	22-28	▬ ▮▮▮▮	10

12.HKS817C RF Device Superiority

12.1.Whole ABS Plastic Mould.
12.2.Variable frequencies depending on the chosen Treatment.
12.3.Frequency of steady emission.
12.4.It does not present any contagious risk.
12.5.Maximum security for the client, default programs
12.6.Permits to adapt the used power used according to the zone and deepness to work.

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